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Quality Assurance Plan United States Department of Energy

Office of Civilian Radioactive Waste Management
Office of Science & Technology and International
Lawrence Livermore National Laboratory

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QUALITY ASSURANCE PLAN

United States Department of Energy
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Lawrence Livermore National Laboratory
Livermore, California

Revision History

Rev. No.	CN No.	Effective Date	Description of Revision/CN
0	0	10/1/04	Initial Issue
0	1	11/5/04	Incorporate corrections to Sections 2.0, 5.0, 7.0, 15.0, and 16.0 recommended by DOE OCRWM OQA.
0	2	11/24/04 DJB 11/23/04	Editorial correction to remove the last sentence of Section 16.0 inadvertently retained in CN 1.

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QUALITY ASSURANCE PLAN

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Revision 0, Change Notice 2

Introduction

Lawrence Livermore National Laboratory (LLNL) is performing work sponsored by the Office of Science & Technology and International (OSTI), which is within the United States Department of Energy (DOE) Office of Civilian and Radioactive Waste Management (OCRWM). This work will be conducted in accordance with the Quality Assurance (QA) guidelines outlined within this Quality Assurance Plan (QAP).

This QAP satisfies requirements of the *OCRWM Quality Assurance Requirements and Description (QARD)* document (DOE/RW-0333P) for the Yucca Mountain Project (YMP). The following table describes the scope of the LLNL OSTI QA Program and its relationship to the QARD.

Quality Assurance Topical Area	*LLNL OSTI QAP Section*	*YMP OCRWM QARD Section*
Organization	1.0	1.0
Quality Assurance Program	2.0	2.0
Design Control	3.0	3.0
Procurement Document Control	4.0	4.0
Implementing Documents	5.0	5.0
Document Control	6.0	6.0
Control of Purchased Items and Services	7.0	7.0
Identification and Control of Items	8.0	8.0
Control of Special Processes	9.0	9.0
Inspection	10.0	10.0
Test Control	11.0	11.0
Control of Measuring and Test Equipment	12.0	12.0
Handling, Storage and Shipping	13.0	13.0
Inspection, Test and Operating Status	14.0	14.0
Nonconformances	15.0	15.0
Corrective Action	16.0	16.0
Quality Assurance Records	17.0	17.0
Audit	18.0	18.0
Software	Sup I	Sup I
Sample Control	Sup II	Sup II
Scientific Investigation	Sup III	Sup III
Field Surveying	Sup IV	Sup IV
Modeling	Sup III	Sup III
Control of the Electronic Management of Data	Sup V	Sup V
High Level Waste Form Production	N/A	App A
Storage and Transportation	N/A	App B
Monitored Geologic Repository	Note 1	App C

Note 1: Applicable elements of the QARD Appendix C have been incorporated in Sections 2.0, 4.0, and 7.0 of the QAP.

This QAP has been prepared in a manner consistent with the applicable QA Program Quality Implementing Procedure (QIP) and recognizes differences between the QA needs of the baseline YMP and those of the exploratory research that is an integral part of the new OSTI Program. The License Application for the repository is imminent and much of

the modeling, testing and data for the baseline program are well established and understood. In contrast, exploratory research directed towards the development of new advanced materials and the processes necessary for production requires sufficient flexibility to enable the beneficial and cost-effective participation by a wide variety of partners from non-DOE federal laboratories, academic institutions, and industry. Many of the innovations needed to move the Repository Science Program into the 21st Century will come from contributors with no previous Yucca Mountain experience, and will require a transitional phase to enable new technologies to be screened and absorbed by the baseline program.

In the early days of the YMP QA Program, the need for such flexibility was recognized and accommodated with phased quality assurance procedures. While all required the standards of good scientific practice, including bound scientific notebooks and calibrated instruments, the level of documentation required to establish the traceability of samples was staged, thereby enabling the screening of a wide range of materials with a reasonable expenditure of available resources. This staged approach will be implemented for the OSTI Program.

Advanced materials and processes are being developed for the OSTI Program. This specific QAP has been developed to encompass those activities essential for conducting such advanced materials science studies. This work includes procurement and preparation of a wide variety of advanced materials, the processing of such materials with a variety of processes (heat treatments, welding, stress mitigation, surface treatment and coating), analysis and characterization of the microstructure and composition of samples of those materials, preparation and analysis of various test environments, testing samples of advanced materials, with a variety of processes. The Principal Investigators, LLNL support organizations, and all LLNL suppliers shall conform to the applicable Sections of this QAP.

QUALITY ASSURANCE POLICY STATEMENT

The U.S. Department of Energy (DOE) has been authorized by Office of Civilian Radioactive Waste Management (OCRWM), with funding through the Office of Science & Technology and International (OSTI), to research, develop, test and analyze materials and methods for use in enhancing their potential industry applications. The DOE established OCRWM to carry out, in part, the management responsibility for programs like OSTI.

The University of California's Lawrence Livermore National Laboratory (LLNL) has a Cooperative Agreement with DOE/OCRWM. Under this Cooperative Agreement, LLNL has established and effectively implements the LLNL Quality Assurance (QA) Program as well as administers and conducts scientific and engineering studies.

It is of utmost importance to LLNL that the data produced under the cooperative agreement is usable for OSTI. Continued funding of any scientific or engineering study under the Cooperative Agreement may be dependent on compliance with the LLNL QA Program. The governing document for the LLNL QA Program is the *DOE/OCRWM Quality Assurance Requirements and Description* (QARD) document (DOE/RW-0333P) implemented for the OCRWM Program. It is from this document that the LLNL QA Program has been developed and quality assurance controls are integrated into LLNL implementing procedures. If work cannot be completed as directed in the implementing procedures, the work shall be suspended. Work shall not resume until appropriate modifications are approved and issued, or other documented resolution is obtained.

LLNL shall implement the LLNL QA Program from the planning stage through work process completion for all LLNL work subject to the requirements of the DOE OCRWM QARD. Compliance with the LLNL QA Program is mandatory when work is defined as QARD applicable, or when the LLNL QA Program is specifically imposed.

David B. McCallen 11/23/04

David B. McCallen Date
OSTI-LLNL Project Manager

Scope

1.0 Organization

LLNL will establish an organizational structure to accomplish the technical and quality objectives established by OCRWM and OSTI for the performance of advanced material science studies assigned by OSTI.

Figure 1 depicts the organization established for the OSTI effort and identifies the line and QA organizations involved in performing the work scope. Quality will be achieved by those assigned the responsibility for performing work. Persons or organizations not directly responsible for performing the work will verify quality achievement.

A brief description of the key LLNL positions identified by Figure 1 follows:

- OSTI-LLNL Project Manager

  The OSTI-LLNL Project Manager (PM) reports to the OCRWM/OSTI Program Deputy Director and is responsible for completion of the OSTI work assigned to LLNL in accordance with the technical and quality requirements established for the work scope. The PM is responsible for execution of the Quality Assurance Program (QA Program), resolving any difficulties and differences of opinion regarding the development and implementation of the QA Program, and interfacing with the Principal Investigators to assure technical and QA matters are properly addressed.

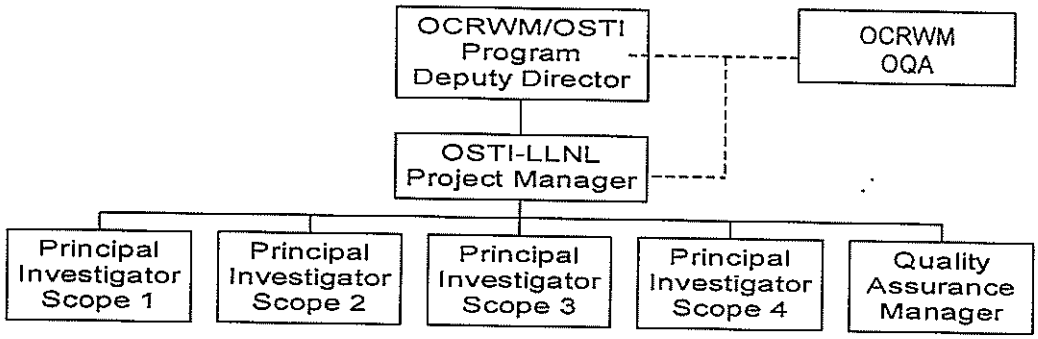
- Quality Assurance Manager

  The Quality Assurance Manager (QAM) is assigned the role of performing the traditional functions of Quality Assurance (QA) for the QA Program. The QAM reports to the PM and will be sufficiently independent from cost and schedule considerations, will have the organizational freedom to effectively communicate with other management positions, will be responsible for interpreting and approving QA Program requirements, will verify proper establishment and execution of the QA Program, and will have the authority to stop work. In addition, a reporting relationship will be established between the QAM and the OCRWM/OQA to assure an independent line of communication on matters related to the adequacy and effectiveness of the QA Program.

- Principal Investigators

  Principal Investigators (PI's) are responsible for managing the performance of material science studies within their area of expertise. The PI's report to the PM and are responsible for the performance of and reporting on scientific experiments, investigations and studies and for performing such work in accordance with the requirements of the QA Program.

Figure 1 OSTI-LLNL Project Organization



LLNL management may delegate any of the functions assigned to them by this QAP to another individual. However, such delegation will be documented and management will retain responsibility for accomplishment of the functions in accordance with the provisions of this QAP.

2.0 Quality Assurance Program

LLNL will establish, implement and maintain a QA Program to control activities that affect the quality of tasks conducted for OSTI. The QA Program will provide control over activities to the extent consistent with their importance. The QA Program will be described by a number of documents including, but not limited to, this QAP, QIP's developed to implement requirements of this QAP, Scientific Investigation Plans (SIP's), and Technical Implementing Procedures (TIP's) developed to control the performance of scientific investigation, calibration, and other activities that affect the quality of tasks performed for OSTI. Work planning documents will be prepared to assure work is accomplished under suitably controlled conditions including the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that any prerequisites have been satisfied.

The use of expert elicitation may be considered provided a systematic process for its conduct is implemented to assure the results of the elicitation accurately reflect data, process and model uncertainty. New data will be reviewed to determine relevance with respect to the experts' assessment, including the need for

reassessment. Software that has not been qualified in accordance with the requirements of *Supplement I, Software*, and unqualified data may be used in the expert elicitation process and the results of the expert solicitation process will be considered qualified. However, the expert elicitation process will not be used to qualify software or unqualified data used as input.

Documents developed to implement the QA Program will be reviewed by qualified individuals other than the preparer and by the QAM to assure they adequately address the applicable technical and quality requirements, will be approved by the PM prior to their distribution for use, and their review and approval will be documented.

Prior to performing activities that affect the quality of tasks conducted for OSTI, personnel will be: 1) evaluated to verify they have the experience, education and proficiency commensurate with the work activity, 2) trained in the procedures and/or instructions that pertain to their work scope, and 3) indoctrinated in the requirements of the QA Program. Verification of experience, education and proficiency and the performance of indoctrination and training will be documented.

The QAM will request OCRWM/OQA to perform or direct the performance of surveillances and audits in accordance with the OCRWM QA Program.

The following QIP's, as a minimum, will be developed to implement this QAP. Additional QIP's may be issued as needed to support changes in the OSTI work scope and/or development of the QA Program. Additional QIP's will be issued in a manner consistent with the applicable QA Program QIP and their omission from this listing will not void either this QAP or the associated QIP.

QIP No.	Title
QIP 1.0	OSTI-LLNL Organizational Structure
QIP 2.0	Indoctrination and Training of Personnel
QIP 2.1	Establishment and Verification of Required Education and Experience of Personnel
QIP 2.2	Planning for Scientific Activities
QIP 4.0	Procurement Document Control
QIP 5.0	Preparing the Quality Assurance Plan and Quality/Technical Implementing Procedures
QIP 5.4	Resolution of Differing Professional Opinion
QIP 6.0	Controlled Documents
QIP 6.1	Document Review
QIP 7.0	Control of Purchased Services
QIP 12.0	Control of Measuring and Test Equipment and Calibration Standards
QIP 15.0	Nonconformances
QIP 16.0	Condition Reporting and Resolution
QIP 17.0	Records Management
QIP SI.0	Software Management
QIP SII.0	Documenting Sample Control
QIP SIII.0	Scientific Notebooks
QIP SIII.1	Technical Reports
QIP SIII.2	Model Reports
QIP SIII.3	Submittal and Incorporation of Data to the Technical Data Management System
QIP SIII.4	Qualification of Unqualified Data
QIP SV.0	Management of OSTI-LLNL Electronic Data

3.0 Design Control

LLNL is not tasked with performing design activities for OSTI. Therefore, this Section of the QAP has not been developed.

4.0 Procurement Document Control

LLNL will establish measures to assure procurement documents, and any changes thereto, for items or services that affect the quality of OSTI activities include appropriate technical and quality requirements.

Procurement documents will include the following as a minimum: 1) a statement of the work scope, 2) applicable technical requirements such as codes, standards, specifications, procedures, instructions, and/or drawings, and 3) applicable quality requirements such as reference to the suppliers documented QA program (approved by OCRWM) or, as an alternative, allowance to perform some or all of the work scope under the LLNL OSTI QA Program (provided the applicable controls from the QA Program are included in the procurement documents, such as the procedures to be followed, calibrated measuring and test equipment to be provided, oversight established to assure material traceabilily and/or compliance

with procedures, etc.); right of access to the suppliers facilities and records for inspection or audit by LLNL and/or OSTI; documentation to be provided to LLNL for information, review, or acceptance; and reporting of nonconformances and LLNL approval of their disposition.

The procurement of analytical services for measurement of properties or other characterization of samples in support of scientific investigations may not require the supplier to have a documented QA program approved by OCRWM, provided such services are controlled in accordance with the requirements of *Section 7.0, Control of Purchased Items and Services*, of this QAP.

Procurement documents, and any changes thereto, will be reviewed by the PI and by the QAM to assure the adequacy of the quality and technical requirements and will be approved by the PM to authorize the expenditure of funds.

5.0 Implementing Documents

LLNL will establish measures to assure work is prescribed by, and performed in accordance with, written implementing documents.

Implementing documents will include information as appropriate to control the performance of work including, but not limited to, a description of the work/activity to be performed; the responsibilities and organizational interfaces affected by the document; technical and quality requirements; qualitative or quantitative acceptance criteria; prerequisites, limits, precautions, environmental conditions; and required records. Implementing documents shall provide a sequential description of the work to be performed including controls for altering the sequence of required inspections, tests, and other operations. Implementing documents will be reviewed, approved and controlled in accordance with the requirements of *Section 6.0, Document Control*, of this QAP.

LLNL personnel will comply with implementing documents, however, when work cannot be accomplished as described in the implementing document, work will be stopped and will not resume until the document is changed to reflect the correct work practices.

6.0 Document Control

LLNL will establish measures to assure documents, including changes thereto, are reviewed for adequacy, approved for release and distributed to and used at the location where work is being performed.

Individuals other than the preparer who are technically competent for the subject area of the document will review documents, including changes thereto, for applicability, correctness, adequacy, completeness, and accuracy. Documents, including changes thereto, will be reviewed by the QAM to verify they include appropriate quality requirements and are in compliance with the requirements of the QA Program and will be approved by the PM for release for implementation. Such review and approval will be documented.

Documents, including changes thereto, either in hardcopy or electronic media, used to perform work will be distributed to, or made available to, and used at, the work location. Documents will be identified with effective dates and electronic database files will be available to determine the current status of documents to be used to perform work. Obsolete or superseded documents will be controlled to assure they are not used to perform work.

7.0 Control of Purchased Items and Services

LLNL will control the procurement of items and services that affect the quality of OSTI activities to assure conformance with requirements specified by procurement documents.

When possible, LLNL will use only suppliers whose QA programs have been evaluated and accepted by OCRWM and who are listed on the OCRWM Qualified Suppliers List (QSL). When LLNL desires to use a supplier not listed on the OCRWM QSL, LLNL will require the supplier to perform work in accordance with the LLNL OSTI QA Program and appropriate controls will be included in the procurement documents developed in accordance with *Section 4.0, Procurement Document Control*, of this QAP.

LLNL will establish mechanisms to accept items and services by verifying suppliers have complied with procurement document requirements. Verification activities include, but are not limited to, review of objective evidence, such as certificates, test or calibration reports, certifications, personnel qualifications, etc.; conduct of source surveillances or audits at the suppliers facilities; or any combination of these activities. Verifications shall not relieve the supplier of the responsibility for the verification of quality achievement. The performance of verification activities and the acceptance of items and services will be documented. Acceptance activities will include the review and acceptance of the disposition of any nonconformances identified by the supplier.

Analytical services in support of scientific investigations may be obtained from suppliers not listed on the OCRWM QSL provided the supplier is required to participate in a quality control sample plan. The quality control sample plan will

be developed prior to issue of the procurement document to the supplier and will address the number and approach (blind, duplicate, spike, etc.) of quality control samples to be submitted, the preparation and analysis of the quality control samples, acceptance criteria, and how the quality control samples, the approach and acceptance criteria provide confidence in the accuracy/precision of the data. The quality control sample analytical results will be received and evaluated against the acceptance criteria prior to using the suppliers' data developed as a result of the analytical service. Analytical data produced, the quality control sample plan, and the quality control sample analytical results and evaluation documentation will be submitted as QA records.

8.0 Identification and Control of Items

LLNL will establish measures to assure that only correct and accepted items are used during the performance of tests and experiments.

Identification will be maintained on the item or documents traceable to the item or in a manner that assures that identification will be established and maintained. Physical marking, when used, will be applied using methods and materials that provide a clear and legible identification, will not be detrimental to the function or service of the item, will not be obliterated or hidden by surface treatments or processing of the item, and will be transferred to each part of an identified item when the item is subdivided.

9.0 Control of Special Processes

LLNL is not tasked with performing special processes for OSTI. Therefore, this Section of the QAP has not been developed. Any special processes performed by suppliers will be controlled in accordance with *Section 4.0, Procurement Document Control*, and *Section 7.0, Control of Purchased Items and Services*, of this QAP.

10.0 Inspection

LLNL is not tasked with performing activities for OSTI that require the performance of inspection. Therefore, this Section of the QAP has not been developed.

11.0 Test Control

LLNL measures for controlling tests will be addressed by the LLNL controls established for the performance of scientific investigations in accordance with *Supplement III, Scientific Investigation*, of this QAP. Therefore, this Section of the QAP has not been developed.

12.0 Control of Measuring and Test Equipment

LLNL will establish measures to assure measuring and test equipment (M&TE) is properly controlled, calibrated, and maintained.

M&TE will be calibrated at prescribed intervals or prior to use against reference standards having traceability to nationally recognized standards. If no nationally recognized standards or physical constants exist, the basis of the calibration will be documented. Calibration standards will have a greater accuracy than the required accuracy of the M&TE being calibrated, unless they do not exist or are unavailable. The use of calibration standards with accuracy equal to the required calibration accuracy may be authorized if they can be shown to be adequate for the requirements and the basis for the use is documented and approved by the PM.

Calibrated M&TE will be labeled, tagged, or otherwise marked or documented to indicate due date or interval of the next calibration and will be uniquely identified to provide traceability to its calibration data. Calibration documentation will include identification of the M&TE calibrated, reference standards used for the calibration, identification of the procedure used to conduct the calibration and resulting calibration data, name of the individual performing the calibration, date of calibration and recalibration due date or interval, a statement of the acceptability of the calibration, and reference to any action taken in connection with out-of-calibration or other nonconforming conditions noted during the calibration. M&TE will be properly handled and stored to maintain accuracy.

The use of M&TE will be documented. M&TE found to be out-of-calibration, producing results known to be in error, or exceeding its calibration due date will be tagged, segregated, or otherwise controlled to prevent use until they have been recalibrated. M&TE found out-of-calibration during recalibration will be evaluated to determine the validity of results obtained using the M&TE since its last valid calibration. The evaluation will be documented.

The procurement and acceptance of supplier calibration services will be controlled in accordance with *Section 4.0, Procurement Document Control*, and *Section 7.0, Control of Purchased Items and Services*, of this QAP.

13.0 Handling, Storage, and Shipping

LLNL will establish measures for the handling, storage, cleaning, packaging, shipping, and preservation of items to prevent damage or loss and to minimize deterioration.

Measures will be conducted in accordance with work implementing documents, shipping instructions, or other specified documents. LLNL will develop specific implementing documents for critical, sensitive, perishable, or high-value articles that may require special handling tools and equipment or protective environments. Such articles will be marked and/or labeled to identify any special controls.

14.0 Inspection, Test and Operating Status

LLNL is not tasked with performing activities for OSTI that require the performance of inspection and operating status. LLNL measures for indicating the status of tests will be addressed by the LLNL controls established for the performance of scientific investigations in accordance with *Supplement III, Scientific Investigation*, of this QAP. Therefore, this Section of the QAP has not been developed.

15.0 Nonconformances

LLNL will establish measures to control items that do not conform to requirements in order to prevent their inadvertent use or installation. Measures will provide for the documentation, identification, segregation, evaluation, and disposition of nonconforming items.

Nonconformances will be documented to clearly identify and describe the characteristics that do not conform to specified criteria. Acceptable dispositions are "use-as-is", "reject", "repair", and "rework." Nonconformance documentation will be reviewed and recommended dispositions will be proposed. Recommended dispositions will be reviewed, evaluated and approved by the PI, the QAM and the PM.

Nonconforming items will be identified by marking, tagging, or other methods that do not adversely affect their use in order to control further processing, delivery, installation, or use pending the evaluation and approval of the disposition. If identification of the item is not practical, then the container, package, or storage area will be identified. Nonconforming items will be segregated, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned. If segregation is impractical or impossible

due to physical conditions, then other precautions will be employed to preclude inadvertent use.

The disposition of "use-as-is" or "reject" for nonconforming items will be identified and documented. The technical justification for dispositions of "use-as-is" will be documented. LLNL will notify OCRWM/OSTI of nonconforming items dispositioned "use-as-is" or "repair" and will not implement the disposition for these items until approval of the disposition is obtained from OCRWM/OSTI.

The QAM will verify implementation of the disposition and upon completion, will complete the nonconformance documentation.

16.0 Corrective Action

LLNL will establish measures to assure that conditions adverse to quality are promptly identified and corrected as soon as possible. Conditions adverse to quality will be identified when a requirement contained in this QAP or an implementing document (e.g., QIP, TIP, etc.) is not met. Conditions adverse to quality will be classified in regard to their significance as either 1) conditions adverse to quality conditions, or 2) significant conditions adverse to quality.

Conditions adverse to quality will be documented and reported to the PI responsible for the condition and to the QAM for tracking. The PI will determine the extent of the condition and complete remedial corrective action as soon as practical. The QAM will concur with the proposed remedial action to assure that the QA Program requirements are satisfied.

The PI and the QAM will evaluate conditions adverse to quality to determine their significance. Significant conditions adverse to quality (e.g., conditions which potentially impact a number of OSTI activities, conditions which indicate extensive QA Program violations, conditions which may impact previously completed YMP work, etc.) will be documented and reported to the responsible management (i.e., PI) for the condition and the PM.

Significant conditions adverse to quality will be evaluated to determine if stopping work is warranted and the decision will be documented. Responsible management will determine the extent and impact of the condition and document the results and complete any remedial action as soon as practical. In addition, the responsible management will determine the root cause of the condition and take corrective action to prevent recurrence as soon as practical. The QAM will concur with the proposed remedial action, the root cause, and the corrective action to prevent recurrence to assure QA program requirements are satisfied.

The QAM will verify implementation of corrective action taken for all reported conditions adverse to quality, including those designated as significant, and upon completion will complete the corrective action documentation.

17.0 Quality Assurance Records

LLNL will establish measures for the specification, preparation, protection, storage, retention, maintenance and turnover of quality assurance records (records).

QAP implementing documents will identify those documents that will become records. Records will be legible, accurate, complete, appropriate for the work, and identifiable to the item or activity to which they apply. Documents will be considered records when they are complete. Records may be originals or copies. Records will be protected from damage, deterioration or loss until they are submitted to the records management system. Corrections to records or documents that will become records will be accomplished by the person authorized to make corrections and will be made by drawing a single line through the changed or incorrect information and inserting the new or corrected information and initialing or signing and dating the entry.

Records will be classified as lifetime or nonpermanent. Lifetime records will be transferred to OCRWM/OSTI for permanent storage as directed by OCRWM/OSTI at an agreed upon schedule. Nonpermanent records will be retained for a period of 3 years. A receipt control and indexing system will be established to aid in determining the status and retrievability of records.

Records will be stored and preserved in predetermined locations. Storage methods will be developed to preclude deterioration of records. Temporary storage of records during processing, review or use until turnover to OSTI (lifetime) or disposal (nonpermanent) will be in containers with a fire rating of 1-hour, as certified by Underwriters Laboratories or equivalent, or dual storage will be provided. Dual storage requires the retention of copies at locations sufficiently remote from each other to eliminate the chance of exposure to a simultaneous hazard.

18.0 Audits

The QAM will request OCRWM/OQA to perform internal audits and surveillances to verify compliance with and the effectiveness of the QA Program. In addition, the QAM will request OCRWM/OQA to perform external audits and surveillances of suppliers furnishing items or services to LLNL. Consequently, the QAP will not address the performance of these activities.

LLNL will establish measures to respond to findings identified by OCRWM/OQA during the performance of audits and surveillances of the LLNL-OSTI QA Program. Such measures will include the investigation of conditions adverse to quality; determination and scheduling of corrective action, including measures to prevent recurrence; and notification of OCRWM/OQA in writing of the actions taken or planned to resolve the conditions adverse to quality.

Supplement I, Software

LLNL will establish measures to control the acquisition, development, modification, control, and use of software.

Note:

- Software that is integral to the operations, maintenance, or calibration of M&TE, and has not been developed or modified by LLNL, is controlled by *Section 12.0, Control of Measuring and Test Equipment*, of this QAP and is exempt from the requirements of this supplement.

- The following types of software are exempt from the requirements of this supplement: operating systems, system utilities, compliers and their associated libraries, word processors, spreadsheets, database managers, E-mail, and other types of automated office support systems. Any applications, other than software routines and macros, developed using these types of commercially available software will meet the requirements of this supplement.

- Software routines or micros that are documented in each product in which they are used and independently verified by visual inspection or hand calculations without recourse to the originator will have limited requirements applied (i.e., identification of software routine or macro, including version; documentation that includes input, computer program generated correct results for the specified input, and verified results; identification of the commercially available software used to develop the routine and macro, including version).

Software acquisition, development, modification, and maintenance will proceed in a planned, traceable, and orderly manner utilizing a defined software life cycle methodology. The methodology will address the following phases: requirements, design, implementation, testing, installation and checkout, operations and maintenance, and retirement.

Software verification and validation activities will be planned, documented, and performed for each software, for software changes, or for those system

configurations that are determined to impact the software. Individuals not associated with development of the software will perform software verification and validation activities, unless such level of independence cannot be achieved. When such level of independence cannot be achieved, an individual associated with the development of the software may perform these activities, provided use of the individual is approved by the PM and the justification for the use of the individual is documented.

A software configuration management system will be established to include configuration identification, configuration change control, and status accounting. Software will be placed under configuration management control as each baseline is approved. Software will not be used in activities subject to this QAP until software configuration management is established.

A software defect reporting and resolution system will be implemented to promptly report and formally resolve software errors and failures. The defect reporting and resolution system will be integrated with the software configuration management system. If a defect is identified in software that adversely impacts previous applications, the condition will be documented and controlled in accordance with *Section 16.0, Corrective Action*, of this QAP.

Software procurement will be controlled in accordance with *Section 4.0, Procurement Document Control*, and *Section 7.0, Control of Purchased Items and Services*, of this QAP. Software suppliers will be required to have policies and procedures in place that meet the applicable requirements of this supplement. Procurement documents will require the submittal of the documentation required by this supplement and will require notification of any software errors and failures identified by the supplier.

Software that was not developed in accordance with the requirements of this supplement will be placed under configuration control prior to use. The user organization will perform, document and provide an independent review and evaluation of the software to determine its adequacy to support software operation and maintenance, to identify activities to be performed and documents required in order for the software to be placed under configuration management. Upon completion of the independent review and approval of these activities, the software will be placed under configuration management control.

The use of software will be controlled and documented. The use of released software will be such that comparable results can be obtained, with any differences explained, through independent replication of the process. Use of software will be independently reviewed and approved to assure the software selected is suitable to the problem being solved. If the intended use of the

software falls outside the range of validation as baselined, changes will be made to the appropriate baseline elements prior to continuing use. Documentation of receipt of software obtained from the configuration management system will be provided and maintained for all software in operation or use.

Supplement II, Sample Control

LLNL will establish measures to receive, identify, handle, analyze, track, store, preserve, ship, and transfer physical samples consistent with their intended use.

Sample identification will assure that traceability is established and maintained from the sample to applicable implementing or specifying documents and the sample will be traceable at all times from its initial collection through final use. Sample identification will be documented and checked before release for use. Identification will be maintained on the sample or if physical marking is either impractical or insufficient, other appropriate means will be employed, such as physical separation, labels or tags attached to containers, or procedural controls. Physical marking, when used, will be applied using materials and methods that provide clear and legible identification, will not be detrimental to the sample content or form, will be transferred to each sample part when the sample is subdivided, and will not be obliterated or hidden by surface treatments or sample preparations unless other identification means are substituted.

Handling, storage, cleaning, packaging, shipping and preservation of samples will be conducted in accordance with implementing documents or other specified requirements. These controls will address any requirements for shelf life, protective or preservative environments, handling tools and equipment, replacement of identification tags or marking, etc., required to maintain the integrity of the samples.

Samples that do not meet the requirements specified in controlling work documents will be processed as nonconforming items in accordance with *Section 15.0, Nonconformances*, of this QAP.

Supplement III, Scientific Investigation

LLNL will establish measures to control the conduct of scientific investigations, including data identification, data reduction, model development and use, and data submittal.

Scientific investigations will be planned and coordinated with the organizations providing input to or using the results of the investigation. Scientific investigations will be performed using implementing documents, scientific

notebooks, or a combination of both. When scientific notebooks are used they will contain a reference to the planning document, identification of samples and measuring and test equipment, and a description of the work, including identification of procurements, methods, computer software, and individuals performing the work and the individual making entries in the notebooks, as it is being performed and the results obtained. Independent qualified individuals will review scientific notebooks to verify there is sufficient detail to retrace the investigation and confirm the results or repeat the investigation and achieve comparable results, without recourse to the original investigator.

Data will be identified in a manner that facilitates traceability to samples, to associated documentation and to its qualification status and this identification and traceability will be maintained throughout the lifetime of the data. Data reduction will be described to permit independent reproducibility by another qualified individual. Qualified individuals other than those who collected or reduced the data will review data reduction to assure technical correctness. Unqualified data (i.e., data not developed in accordance with the requirements of this QAP) may be qualified provided the qualification process is planned and documented and by completing one or more of the following methods:

- Verifying that the controls under which the data were generated are similar in scope, requirements and implementation to this QAP.
- Evaluation of corroborating data; the basis for selection of the corroborating data is clearly explained and justified.
- Confirmatory testing.
- Peer review.
- Technical assessment to independently evaluate data.

Model development and approaches to validation will be planned, controlled, and documented. Planning for model validation will identify the validation methods and validation criteria used. Model validation may be completed after documentation of the model provided this sequence is described by the planning document.

Documentation of models will include a definition of the objective or intended use of the model, a description of the conceptual model and scientific basis, results of literature searches and other background information, identification of inputs and their sources, identification of and rationale for assumptions used to develop or apply the model, discussion of the mathematical and numerical methods used in the model, identification of any associated software used or computer calculations performed, discussion of initial and/or boundary conditions, discussions of model limitations and uncertainties, and identification of the originator, reviewer and approver.

The intended use and importance of the model for assessing system/experiment performance will determine the appropriate level of confidence for the model (i.e., models most relied upon to establish performance will be validated with the highest levels of confidence).

Criteria for model validation will be established to reduce the uncertainties in the model and to demonstrate the phenomenon, process, or system being represented by the model is sufficiently well understood to support the model's intended use. Model validation criteria will address criteria used to establish the adequacy of the scientific basis for the model, will be consistent with the model application and justified in the model documentation, will demonstrate that the model is sufficiently accurate for its intended use, will be consistent with parameter uncertainties and justified in the model documentation, will define the importance of the model for assessing system/experiment performance, will describe the level of confidence for the model, and will define the supporting information needed to substantiate validation.

Model progression, usually from conceptual model to mathematical model to process model to abstraction model to system model, will exist. A conceptual model is validated when its implementation as a mathematical, process, abstraction, or system-level model is validated. Technical review through publication in a refereed professional journal or review by an external agency may be used to corroborate model validation when used in conjunction with one or more of the following:

- Corroboration of model results with data acquired from field experiments, analogue studies, laboratory experiments, or subsequent relevant observations. Data used to develop and calibrate a model will not be used to validate a model.
- Peer review and independent technical review.
- Performance confirmation studies using validation-test model predictions prior to comparison with field or laboratory data.
- Comparison of model results with other model results obtained from implementation of an alternative model.
- Calibration with experimental data sets, including the review of model calibration parameters for reasonableness and consistency in explanation of all relevant data.

Scientific investigation planning will be controlled in accordance with *Section 2.0, Quality Assurance Program*, of this QAP. Technical Reports will be controlled in accordance with *Section 6.0, Document Control,* of this QAP. Computer software used to develop or execute models will be qualified in accordance with *Supplement I, Software*, of this QAP. Samples will be controlled in accordance with *Supplement II, Sample Control*, of this QAP. The electronic

management of data will be controlled in accordance with *Supplement V, Control of the Electronic Management of Data*, of this QAP.

Supplement IV, Field Surveying

LLNL is not tasked with performing field surveys for OSTI. Therefore, this Section of the QAP has not been developed.

Supplement V, Control of the Electronic Management of Data

LLNL will establish measures to control the management of data that either exist or are used in an electronic format. This includes data developed as an output of scientific investigation or performance assessment modeling and analysis.

Data will be suitably protected from damage and destruction during their prescribed lifetime and will be readily retrievable. Descriptions will be prepared to identify how data will be stored with respect to media, conditions, location, retention time, security and access. Storage and transfer media will be properly identified as to source, physical and logical format, and relevant date. The completeness and accuracy of data input and any subsequent changes to the data, as well as the security and integrity of the data, will be maintained. Data transfers will be error free, or within a defined permissible error rate, to assure no information is lost in transfer and that the input is recoverable from the output.